UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

FERRING PHARMACEUTICALS INC.,	)	
Plaintiff and Counterclaim-Defendant,	)	
v.	)	Civil Action No. 13-cv-12553-NMG
BRAINTREE LABORATORIES, INC.,	)	
Defendant and Counterclaim-Plaintiff.	)	

BRAINTREE LABORATORIES, INC.'S REPLY
IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT

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Defendant and Counterclaim-Plaintiff Braintree Laboratories, Inc. ("Braintree") respectfully submits this reply brief in support of its motion for summary judgment and in response to the opposition filed by Plaintiff and Counterclaim-Defendant Ferring Pharmaceuticals Inc. ("Ferring").

I. FERRING HAS NOT PRESENTED ANY TRIABLE CLAIMS BASED ON ITS ALLEGATIONS THAT BRAINTREE FALSELY EQUATED PREPOPIK AND PICO-SALAX.

Ferring attempts two arguments to save those of its claims that are grounded on its allegation that Braintree falsely equated Pico-Salax and Prepopik. First, Ferring attempts to obfuscate the undeniable, and admitted, equivalence of Pico-Salax and Prepopik by shifting focus to the irrelevant assertion that the identical drug is sometimes used differently in the United States and Canada. In the course of doing so, however, Ferring is forced to admit that Pico-Salax and Prepopik are in fact the same, and that Ferring itself has stated as much. Second, Ferring relies on its own *allegations*, but no admissible evidence, that individual Braintree sales representatives have orally described Prepopik as dangerous or unsafe on a handful of occasions. But Ferring has not come forward with admissible evidence to support these allegations, which are insufficient in any event to make out a valid Lanham Act claim.

A. Ferring Has Admitted the Equivalence of Pico-Salax and Prepopik, and its Irrelevant Arguments Regarding Different Uses of the Drug in the United States and Canada Cannot Save its Claims.

As noted in Braintree's opening brief, the sole "evidence" that Ferring submitted with its complaint is a copy of the Canadian Newsletter, with a handwritten annotation stating "Pico-Salax = Prepopik." Plaintiff further accused Braintree of disseminating the Canadian Newsletter to doctors. As Braintree pointed out, the underlying flaws with Ferring's theory that this equation is false are that Ferring itself has stated that Pico-Salax and Prepopik are the same, and that, as a matter of scientific fact, they are the same. Ferring's opposition admits that Ferring

itself has stated that Pico-Salax and Prepopik are the same and that the difference is merely one of branding, including in a press release that it issued. Ferring admits, for example, that it issued a press release stating, "Prepopik is available in Canada (marketed under the name Pico-Salax)." Ferring tells the Court, however, that it should ignore this admission, because its own press release was wrong. Thus, Ferring's remarkable position is that Braintree can be found liable for repeating a statement – "Pico-Salax = Prepopik" – that Ferring itself had issued and publicized – "Prepopik is available in Canada (marketed under the name Pico-Salax)."

Even putting aside the absurdity of suing Braintree for repeating what Ferring has said about its own product, Ferring further admits in its opposition papers that Pico-Salax and Prepopik are in fact chemically equivalent. Thus, Ferring has both publicly proclaimed that Pico-Salax and Prepopik are the same, and now admits in opposing summary judgment both that public proclamation and that Pico-Salax and Prepopik are the same substance. These concessions eliminate any potential that a reasonable fact finder could conclude that Braintree violated the Lanham Act by writing, "Pico-Salax = Prepopik," even if one assumes that this single handwritten note is attributable to Braintree.

Forced to make these admissions, Ferring tries to distract from the truth of the "Pico-Salax = Prepopik" statement, which it concedes, but about which it nevertheless complains, by focusing on the different ways the identical drug is sometimes used in the two countries. Specifically, Ferring points out that Pico-Salax/Prepopik is available in the United States only through prescriptions, but is available over-the-counter in Canada; that Canadian users are instructed to drink more liquid with Pico-Salax/Prepopik than are users in the United States; and that the approved uses in Canada for Pico-Salax/Prepopik include not just cleansing the colon for adult colonoscopies as in the United States, but also cleansing the colon for x-rays and surgery, and for

pediatric use. Based on these differences in use, Ferring "confesses" its own supposed error when it issued a press release equating the two – although Ferring says nothing about ever having done anything to correct this supposed misstatement in the public record, and does not claim that it ever told Braintree about Ferring's own "false" information prior to filing its opposition papers.

As for its supposed "error," Ferring states that "Statements by a salesman [apparently referring to its own press release] lack foundation to establish a scientific fact." (Opp. at 3.) But Ferring ignores that the FDA itself has repeatedly pointed out and relied on the fact that Prepopik and Pico-Salax are the same, based on Ferring's representations to it. For example, the FDA's publicly available Clinical Pharmacology and Biopharmaceutics Review, provided in conjunction with the FDA's approval of Prepopik/Pico-Salax in the United States, states as follows under the heading "What is the regulatory background?":

> This product [Prepopik] is approved for use for colon cleansing in Europe and Canada under the names of Picolax, PicoSalax or Pico-Salax. In this submission, the sponsor [Ferring] is seeking an approval of this product in the United States for the same indication.

(Decl. of Joshua L. Solomon, ¶ 6, filed herewith.) Similarly, the FDA's Statistical Review, also conducted in the context of the approval process, states:

> The [Prepopik] formulation contains the same 3 active ingredients (sodium picosulfate, magnesium oxide and citric acid) in the same milligram proportions as products sold for more than 3 decades under the trade names Picolax and Picosalax/Pico-Salax, also manufactured by Ferring.

(*Id.* ¶ 7.)

Furthermore, Ferring avoided the need to conduct dose ranging studies when obtaining approval for Prepopik/Pico-Salax in the United States, on the basis of dosing studies previously conducted on the substance in Canada. As the FDA stated in its Clinical Pharmacology and Biopharmaceutics Review, "The sponsor [Ferring] did not conduct a dose finding study. The two proposed dosing regiments were studied in two phase 3 trials, which were the same regimens as

those approved in Canada." (*Id.* ¶ 4.) The FDA repeated that information under the heading "What is the sponsor's dose selection rationale?" (*Id.* ¶ 5.) Ferring's conclusory assertion that its own press release was mistaken when it equated Prepopik and Pico-Salax ignores this further evidence of its own and the FDA's statements that they are the same. Contrary to Ferring's present effort to split hairs between composition and usage, during formal approval processes with the FDA, Ferring equated Prepopik with Pico-Salax for all purposes, thereby minimizing some of its burdens on dosing studies. In other words, Ferring had no problem equating Prepopik with Pico-Salax until the Canadian Newsletter said really bad things about Pico-Salax. Yet Ferring has introduced no evidence that it ever corrected its position with the FDA equating the two.

In any event, even with respect to different uses on which Ferring relies, Ferring provides no evidence that these different ways in which Pico-Salax/Prepopik can be used make any material difference with respect to the incidents reported in the Canadian Newsletter. For example, Ferring offers no evidence that it matters one bit whether Pico-Salax/Prepopik is taken for a colonoscopy or for an x-ray. Ferring offers up some theories for why some of the differences in use might matter, but no evidence that it does. Moreover, nowhere does Ferring allege, or more importantly, provide any evidence, that Braintree made any false representations regarding the procedures for which Pico-Salax/Prepopik are used, the availability of Pico-Salax/Prepopik over-the-counter vs. by prescription, or the amount of liquid that must be taken with Pico-Salax/Prepopik.

Pico-Salax and Prepopik are in fact the same. Ferring has said so. The FDA has said so. Braintree cannot be liable for saying so. The First Amendment, and the permissible rough and tumble of ordinary competition, preclude the use of litigation to chill the use of scientific literature and a competitor's own statements against it. Ferring may regret its own public equation of Pico-Salax to Prepopik, but cannot hold Braintree liable for that regret.

B. Ferring's Reliance on its Complaint's *Allegations* of Oral Statements Does Not Satisfy its Burden to Provide Admissible, Sufficient Evidence in Support of its Claims for False Advertising.

Stuck with its own professed, and true, proclamations that Pico-Salax and Prepopik are the same, Ferring attempts to shift focus to its complaint's vague allegations that Braintree went further by also representing that Pico-Salax/Prepopik is dangerous or unsafe. Whereas its complaint refers vaguely to oral statements "related" to or made "in conjunction with" the alleged statement that "Pico-Salax = Prepopik," now in its opposition Ferring asserts that its allegations "are largely based on Braintree's oral statements." (Opp. at 1.) Notwithstanding this shift in theory, Ferring provides no admissible evidence of such "oral statements," as was its burden in opposing a motion for summary judgment. Furthermore, even the inadmissible evidence it does provide would be insufficient to demonstrate a Lanham Act violation on this theory.

The section of Ferring's opposition (II.A.4) arguing that its claim is based on more than Braintree's alleged statement that "Pico-Salax = Prepopik" consists entirely of a repetition of its complaint's *allegations* to the effect that Braintree orally depicts Prepopik/Pico-Salax as dangerous or unsafe. In doing so, Ferring ignores black-letter law that one cannot successfully oppose summary judgment with resort to a pleading's allegations, even if the allegations are more specific than the vague, conclusory allegations that Ferring included in its complaint:

> Neither wishful thinking nor "mere promise[s] to produce admissible evidence at trial," *Garside*, 895 F.2d at 49, nor conclusory responses unsupported by evidence, *Ayer v. United States*, 902 F.2d 1038, 1044–45 (1st Cir.1990), will serve to defeat a properly focused Rule 56 motion. After all, one who opposes a Rule 56 motion "may not rest upon her laurels (or her pleadings)." *Mack*, 871 F.2d at 181. Rather, the opponent must pull the laboring oar and "set forth specific facts showing there is a genuine issue for trial." Fed. R. Civ. P. 56(e). This requires hard evidence of a material factual dispute; the opposition cannot be "conjectural or problematic [but] must have substance." *Mack*, 871 F.2d at 181. Evidence which is "merely colorable, or is not significantly probative" will not preclude summary judgment."

Griggs-Ryan v. Smith, 904 F.2d 112, 115 (1st Cir. 1990); *see also Nna v. Am. Standard, Inc.*, 630 F. Supp. 2d 115, 124 (D. Mass. 2009). Rather, Ferring's burden was to come forward with *evidence*, not merely allegations, to support it claims. Its repeated resort to its own complaint is thus meaningless. Yet Ferring's opposition offers no discussion of any evidence behind these allegations. In fact, clearly uneasy about its own supporting submissions – elsewhere, Ferring refers to the contents of the declarations it files as merely "allegations" (Opp. at 19) – Ferring's opposition brief does not even discuss the contents of the declarations that supposedly support Ferring's theory. Instead, it attempts to convince the Court that its claims involve more than statements to the effect of "Pico-Salax = Prepopik" by reference not to its proffered evidence, but merely to the complaint alone.

But even if the Court were to examine the declarations to explore arguments based on them that Ferring's opposition did not make, Ferring would still fall short of adequately supporting its claims. To the extent the declarations purport to support the allegation that certain individual Braintree sales representatives described Prepopik/Pico-Salax as dangerous or as causing particular maladies, they consist of no more than inadmissible hearsay. Specifically, they include statements by Ferring sales personnel to the effect that those personnel were told by unidentified doctors in unidentified medical offices that unidentified Braintree sales representatives made particular statements. In some cases, the reports from Ferring sales staff purport to repeat statements not from the unidentified doctors, but from unidentified medical assistants or schedulers who, in turn, purportedly repeated what the unidentified doctors said about what the unidentified Braintree representatives said. Such hearsay – and, especially, the hearsay upon hearsay – is insufficient to defeat a motion for summary judgment. *Bennett v. Saint-Gobain Corp.*, 507 F.3d 23, 28-29 (1st Cir. 2007) ("But the plaintiff did not offer an affidavit from any person who actually had heard the

alleged statement. Given this omission, we ruled that the statement was hearsay under Federal Rule of Evidence 801(c) and reiterated that it is black-letter law that hearsay evidence cannot be considered on summary judgment. The scenario here demands the same result. The plaintiff had no first-hand knowledge of Feagans's alleged remarks, nor did he tender an affidavit from Porter or any other percipient witness attesting to them. Thus, the comments attributed to Feagans in Porter's grievance were hearsay." (internal citation and editing omitted)); *Davila v. Corporacion De Puerto Rico Para La Difusion Publica*, 498 F.3d 9, 17 (1st Cir. 2007) ("It is black-letter law that hearsay evidence cannot be considered on summary judgment."); *Garside v. Osco Drug, Inc.*, 895 F.2d 46, 50 (1st Cir. 1990) ("Hearsay evidence, inadmissible at trial, cannot be considered on a motion for summary judgment."). Nor do Ferring's opposition papers provide *any* suggestion that these hearsay offerings could be in an admissible form for trial. Ferring has not stated, for example, that the third-party doctors and non-doctor personnel would be prepared to testify to what the Ferring sales representatives claimed they were told. Nor does Ferring offer any explanation for why it did not produce these supposed reports in admissible form with its opposition.

Furthermore, even were these hearsay-laden declarations admissible, they would be insufficient to save Ferring's claims on a theory that oral statements by individual Braintree sales representatives made for a Lanham Act violation. The declarations provide no information about who the Braintree sales representatives were who allegedly made the statements. The declarations provide no information about who the doctors or other personnel were who supposedly heard or heard of them. Through such nimble language as "Suprep sales representatives made him [a doctor] feel" a certain way, (Wilmer Decl. ¶ 11), and "*[i]t is my understanding* that [safety] concerns arose from his [a doctor's] interaction with the Suprep sales representative," (Factor Decl. ¶ 9), the declarations also generally avoid committing to any specific representations that Braintree

sales representatives supposedly made. In some cases, they do not even reveal whether the unidentified Braintree sales representative said anything in particular, or whether the unidentified doctors or other personnel merely drew their own "dangerousness" inferences from the facts reported in the Canadian Newsletter combined with the undeniable fact that Pico-Salax and Prepopik are the same thing. In short, Ferring's offerings are not just hearsay, but hearsay of the most unreliable kind, as they lack of information as to the identities of the declarants or recipients of the information, and the characterizations of the discussions result from a game of telephone. In the end, to the extent it relies on these declarations, Ferring has ignored First Circuit law requiring that an opposition to a motion for summary judgment "cannot be conjectural or problematic but must have substance," and that proffered "[e]vidence which is merely colorable, or is not significantly probative will not preclude summary judgment." *Griggs-Ryan*, 904 F.2d at 115.

In addition, the declarations appear to report occurrences in only twelve medical offices throughout the country (without identifying information about the particular offices or doctors), and contain no information as to whether it was one Braintree sales representative who supposedly made the statements, twelve separate representatives, or some number in between. This shortcoming is critical, as a small handful of alleged oral statements to particular audiences within a much broader market, which is all the Ferring has offered even if it had otherwise adequately supported and detailed them, do not create a Lanham Act violation. The Lanham Act requires that the allegedly false statement appear in an "advertisement" or "promotion," both of which have been repeatedly interpreted to involve widespread dissemination to the public or a significant portion of the relevant market. As a result, sporadic statements in private settings are insufficient. Thus, "[g]enerally, a statement made by an individual salesperson to an individual potential customer is not actionable." *BellSouth Adver. & Pub. Corp. v. Lambert Pub.*, 45 F. Supp. 2d 1316,

1322-24 (S.D. Ala. 1999), *aff'd*, *BellSouth Adv. v. Lambert Pub.*, 207 F.3d 663 (11th Cir. 2000). And as the Second Circuit has held, "[p]roof of widespread dissemination within the relevant industry is a normal concomitant of meeting this requirement," and that "businesses harmed by isolated disparaging statements do not have redress under the Lanham Act." *Fashion Boutique of Short Hills, Inc. v. Fendi USA, Inc.*, 314 F.3d 48, 57 (2d Cir. 2002). Accordingly, that court affirmed a grant of summary judgment where "[plaintiff] presented a total of twenty-seven oral statements regarding plaintiff's products in a marketplace of thousands of customers," as "[s]uch evidence is insufficient to satisfy the requirement that representations be disseminated widely in order to constitute 'commercial advertising or promotion' under the Lanham Act." *Id.* at 58. Ferring's offering falls far short of even the 27 instances that were insufficient in that case. *See also, e.g., Am. Needle & Novelty, Inc. v. Drew Pearson Mktg., Inc.*, 820 F. Supp. 1072, 1077-78 (N.D. Ill. 1993) ("As defined by Webster's, advertising is 'the action of calling something to the attention of the public [especially] by paid announcements.' The concept of public notification also occurs in the definitions of 'advertise' and 'advertisement.' Similarly, the definition of 'promotion' utilizes the term 'publicity.' Nothing in the Lanham Act suggests that 'advertisement' and 'promotion' should be given any interpretation other than their plain and ordinary meanings, which include the notion of public dissemination of information." (internal citations omitted; editing in original)). Applying these principles to another case in which the plaintiff came forward with nothing but hearsay statements regarding unidentified sales personnel making statements to individual customers, as is also the case here, another court held as follows:

> The alleged statements made by individual Home Depot sales personnel are not commercial advertising or promotion because the statements were not sufficiently disseminated to the purchasing public. In order to qualify as advertising or promotion, statements must be widely disseminated and "part of an organized campaign to penetrate the relevant market." *Fashion Boutique*, 314 F.3d at 57; *Auto-Chlor Sys. of Minn., Inc. v. JohnsonDiversey*, 328 F. Supp. 2d 980, 1019 (D.

> Minn. 2004). Thus, the statements must be directed at a class or category of consumers, not simply particular individuals. *Podiatrist Ass'n*, 332 F.3d at 19. . . . ***[O]ther than hearsay statements, Optimum has failed to present any evidence that these statements were made and has failed to identify any particular employee or employees who made these representations.*** Furthermore, Optimum has not presented any evidence that these statements were part of an organized campaign to penetrate the market place. Unless the relevant purchasing market is particularly limited, which is not the case here, ***isolated statements by sales personnel to individual customers do not satisfy the requirement of sufficient dissemination***. *Fashion Boutique*, 314 F.3d at 58 (oral statements by sales personnel in a marketplace of thousands of customers insufficient to establish widespread dissemination); *First Health Group Corp. v. BCE Emergis Corp.*, 269 F.3d 800, 803 (7th Cir. 2001) ("Advertising is a form of promotion to anonymous recipients, as distinguished from face-to-face communication."); *Garland*, 895 F. Supp. at 279 (misrepresentation directed only at one customer did not disseminate the misrepresentation sufficiently to the public); *Medical Graphics Corp. v. SensorMedics Corp.*, 872 F. Supp. 643, 650 (D. Minn. 1994) (statements by one sales representative to individual potential customer not actionable where potential market for medical products was large). Thus, even if Optimum had presented admissible evidence of particular false or misleading statements made by Home Depot sales personnel to individual customers, there is no evidence that these statements were disseminated sufficiently to constitute commercial advertising or promotion. Summary judgment on Optimum's false advertising claim based on representations made by Home Depot sales personnel is warranted.

Optimum Technologies, Inc. v. Home Depot USA, Inc., 1:04 CV 3260 TWT, 2005 WL 3307508, at *5 (N.D. Ga. Dec. 5, 2005), *aff'd in part*, 217 F. App'x 899 (11th Cir. 2007).

Nor can Ferring rely on any exception to the widespread-dissemination requirement for such situations as "where the customer market is particularly small," as it is Ferring's burden in such situations "to put forward . . . evidence regarding the number of potential consumers in the [relevant] market or the size or importance of the consumers to whom the statements were disseminated." *Schutz Container Sys., Inc. v. Mauser Corp.*, 1:09-CV-3609-RWS, 2012 WL 1073153, at *31 (N.D. Ga. Mar. 28, 2012).

C. Ferring's Resort to Rule 56(d) Cannot Save its Claims.

Finally, Ferring has not sufficiently supported its request under Rule 56(d) for a denial of summary judgment to permit it to engage in discovery. First, Ferring's admission that it has

asserted publicly that Prepopik and Pico-Salax are the same, and its concession in its opposition papers that they are chemically equivalent, make implausible any potential that discovery would help Ferring bolster its claim that statements to the effect of "Pico-Salax = Prepopik" are false. To the extent Ferring is asserting that its own equating of Pico-Salax and Prepopik was erroneous, it would have access to evidence about its own statements and products that would demonstrate that error. Yet far from coming forward with such evidence, it has instead conceded that the two are the same substance. Nor has Ferring in any way demonstrated that its ability to support its assertion that Pico-Salax/Prepopik is *used* differently in the United States and Canada, even if relevant, depends in any way on its need for discovery. *See Zurich Am. Ins. Co. v. Watts Regulator Co.*, 860 F. Supp. 2d 78, n.6 (D. Mass. 2012) (Gorton, J.) (granting motion to for summary judgment where there was no plausible basis to conclude that additional discovery would influence the outcome of summary judgment); *Reich v. United States Dept. of Energy*, 784 F. Supp. 2d 15, 24 (D. Mass. 2011) (Gorton, J.) (granting motion for summary judgment where it was "difficult to imagine what additional information [the Plaintiff] would extract from depositions . . . or from written discovery").

With respect to its theory that individual Braintree sales personnel have made disparaging oral remarks about Pico-Salax/Prepopik, Ferring has similarly failed to provide an adequate basis for its assertion that it is unable to marshal evidence for lack of discovery. As discussed at length above, even if Ferring, through discovery or otherwise, were able to convert its inadmissible declarations on this point into admissible evidence, that evidence would not suffice to support Ferring's Lanham Act claim, as the isolated statements on which Ferring relies do not satisfy the advertising or promotion requirements for such a claim. Thus, the discovery that Ferring seeks is not "foreseeably capable of breathing life into [its] claim." *Resolution Trust Corp. v. N. Bridge*

Assocs., Inc., 22 F.3d 1198, 1207 (1st Cir. 1994)." Nor has Ferring explained why it requires discovery to convert such statements into admissible evidence. As the declarations themselves make clear, Ferring has access to the declarants whom Ferring claims would support its theory, yet offers no explanation for why it did not provide admissible evidence from them. Ferring also does not state, and cannot state, what sort of discovery it would need to add up the size of the marketplace, in order to justify its failure to prove widespread dissemination. With respect to its Rule 56(d) request, Ferring's obligation was to "show[] by affidavit or declaration that, *for specified reasons*, it cannot present facts essential to justify its opposition." Fed. R. Civ. P. 56(d) (emphasis added). A declaration from its litigation counsel that does nothing more than list topics of discovery that Ferring wishes to take does not satisfy this burden. Furthermore, Ferring's wishful statement about what the state of its case would be "[i]f Ferring is able to substantiate the allegations contained in the supporting declarations through discovery," (Opp. at 19), is no substitute for Rule 56(d)'s requirement that Ferring articulate by affidavit or declaration that, "for specified reasons," it is not currently able to support its claims.

Particularly in light of Ferring's admissions that Pico-Salax and Prepopik are in fact the same substance, Ferring's failure to articulate both the basis for its inability to support its claims and a plausible theory that discovery might support, makes its request for discovery nothing more than an unsupported hopeful plea that a fishing expedition will provide something helpful to it. Rule 56(d) requires more.

II. FERRING HAS PROVIDED NOTHING MORE THAN UNSUPPORTED ALLEGATIONS THAT BRAINTREE'S EFFICACY AND SUPERIORITY CLAIMS ARE FALSE.

In its Complaint, Ferring advanced the demonstrably false allegation that "[t]here are no head-to-head studies comparing the effectiveness of Prepopik and Suprep." Compl. ¶ 53. In response, Braintree furnished incontrovertible, publicly-available evidence of a head-to-head

comparison reported in the American Journal of Gastroenterology, which concluded, among other things, that Suprep is superior to Prepopik. (Arnould Aff. Ex. 11.) Now, Ferring changes tack in an eleventh-hour attempt to salvage its Lanham Act claim:

First, Ferring disingenuously recasts Braintree's efficacy and superiority claims as so-called "establishment claims" – i.e., claims that say, in substance, "tests or studies prove a certain fact" – as opposed to "non-establishment claims" – i.e., general claims of superiority. *See Gillette Co. v. Norelco Consumer Products Co.*, 946 F. Supp. 115, 212 (D. Mass. 1996). But Braintree's efficacy and superiority claims about which Ferring complains are, on their face, "non-establishment claims" in that they generally state that Suprep is superior to Prepopik, and do not identify a connection to any particular test or study, including the reported head-to-head comparison. Accordingly, Ferring must affirmatively prove that Braintree's efficacy and superiority claims are actually false. *Id.* That, Ferring cannot do.

Second, Ferring harps on a single handwritten annotation about Prepopik on a single copy of Braintree's Comparison Detailer – "Plus only 74% efficacy compared to 98% with Suprep!" However, the law is clear that isolated statements by sales personnel to individual customers *do not* constitute "commercial advertising or promotion" as required under the Lanham Act. *See, e.g.*, *Ultra-Temp Corp. v. Advanced Vacuum Sys., Inc.*, 27 F. Supp. 2d 86 (D. Mass. 1998). And, in any event, the annotation does not support Ferring's contention that Braintree's efficacy and superiority claims are baseless, nor has Ferring adduced a shred of admissible evidence to prove that the annotation is reasonably attributable to Braintree.

Third, Ferring once again improperly relies upon its own *allegations* that individual Braintree sales representatives are apparently using the Comparison Detailer to represent that

Suprep is safer and more effective than Prepopik. But Ferring has not come forward with admissible or sufficient evidence to support these allegations.

None of these arguments helps Ferring to overcome the legal bars to establishing its false advertising claims based on Braintree's Comparison Detailer and Clean Freak advertisement. The Court should accordingly grant Braintree's motion for summary judgment on those claims.

A. Ferring Cannot Prove That Braintree's Efficacy And Superiority Claims Are Actually False.

Braintree's efficacy and superiority claims in the advertisements about which Ferring complains are general superiority and efficacy claims, without reference to any studies. They thus constitute non-establishment claims. As this Court explained in *Gillette*, upon which Ferring relies in its opposition, "[a]n establishment claim is one that says, in substance, that 'tests or studies prove a certain fact. A non-establishment claim is a general claim of superiority." 946 F. Supp. at 121. Notwithstanding Ferring's unsubstantiated protestations to the contrary, Braintree's Comparison Detailer and Suprep Clean Freak advertisement neither explicitly nor implicitly state that the head-to-head study reported in the American Journal of Gastroenterology (or, for that matter, any other test or study) proves Suprep's superiority over Prepopik. Indeed, as Ferring itself acknowledges, both advertisements, "taken as a whole" simply "suggest that Suprep is safer and more effective than Prepopik." (Compl. ¶ 63; *see also id.* ¶ 76.) Accordingly, Braintree's efficacy and superiority claims plainly qualify as non-establishment claims.

This Court has held that where non-establishment claims are at issue, a plaintiff challenging them must "affirmatively prove defendant's product equal or inferior." *Gillette*, 946 F. Supp. at 121. But Ferring provides no admissible evidence to satisfy this burden. Indeed, nowhere does Ferring *even allege* that Prepopik is equal or superior to Suprep in terms of its

efficacy or safety profile. (Compl. ¶¶ 43-80, 97-103.) Instead, stuck with an evidentiary burden it cannot meet, Ferring attempts to distract the Court by recasting Braintree's statements as rising and falling entirely on the head-to-head study – ironically, a study that, until now, Ferring claimed did not exist. In so doing, Ferring attempts to make an end run around its burden of affirmatively proving that Braintree's efficacy and superiority claims are false. As this Court has held, "[a] plaintiff contesting an establishment claim bears a different burden from that to be borne by a plaintiff contesting a non-establishment claim":

> A plaintiff's burden in proving literal falsity thus varies depending on the nature of the challenged advertisement. Where the defendant's advertisement claims that its product is superior, plaintiff must affirmatively prove defendant's product equal or inferior. Where . . . defendant's ad explicitly or implicitly represents that tests or studies prove its product superior, plaintiff satisfies its burden by showing that the tests did not establish the proposition for which they were cited. We have held that a plaintiff can meet this burden by demonstrating that the tests were not sufficiently reliable to permit a conclusion that the product was superior.

Gillette, 946 F. Supp. at 121.

It is therefore unsurprising that in opposing summary judgment, Ferring disingenuously focuses on its apparent need to take discovery on the testing methodology and reliability of the head-to-head comparison. But, as described above, Braintree's superiority and efficacy claims simply and plainly do *not* hinge on the head-to-head comparison. Braintree's citation to the comparison in its summary judgment motion addressed Ferring's specific, false, and unqualified allegation that no such comparison exists: "There are no head-to-head studies comparing the effectiveness of Prepopik and Suprep." (Compl. ¶ 53.) But the advertisements about which Ferring complains do not cite to the study or otherwise claim that a study made a particular showing. Rather, Braintree's statements are simply stand-alone, general claims of superiority, which Ferring simply cannot – and has not even attempted – to disprove. Thus, even if Ferring

could debunk the head-to-head comparison, it still would not have satisfied its burden to show that its product is equal to or better than Suprep.

B. Ferring Cannot Sustain Its Lanham Act Claim on the Basis of a Single Handwritten Annotation.

Ferring further attempts to salvage its Lanham Act claims on the basis of a single handwritten annotation about Prepopik on a copy of the Comparison Detailer, reading "Plus only 74% efficacy compared to 98% with Suprep!" But the law is clear: isolated statements like the annotation are insufficient to sustain a Lanham Act claim. *See, e.g., Ultra-Temp Corp.* (holding that single representation to customer was an isolated statement not disseminated sufficiently to the purchasing public to constitute "advertising" or "promotion" to support a claim under Lanham Act for false advertising). Indeed, the "touchstone of whether a defendant's actions may be considered 'commercial advertising or promotion' under the Lanham Act is that the contested representations are part of an organized campaign to penetrate the relevant market." *Fashion Boutique of Short Hills, Inc. v. Fendi USA, Inc.*, 314 F.3d 48, 57 (2d Cir. 2002).

Here, even assuming the annotation is reasonably attributable to Braintree, Ferring provides no admissible evidence that the handwritten annotation was part of an organized campaign by Braintree to penetrate the relevant marketplace, or that the single handwritten statement was disseminated widely enough to constitute "commercial advertising or promotion." For this reason alone, Ferring's attempt to sustain its Lanham Act claim on the basis of the handwritten annotation fails. *See Prof'l Sound Servs. v. Guzzi*, 349 F. Supp. 2d 722, 729 (S.D.N.Y. 2004) (holding isolated statement to a single customer insufficient to state Lanham Act claim); *Am. Needle & Novelty, Inc. v. Drew Pearson Mktg., Inc.*, 820 F. Supp. 1072, 1077-78 (N.D. Ill. 1993) ("To permit a single private correspondence to constitute either ["advertising" or "promotion"] for purposes of § 43(a)(2) liability would render their use superfluous and would

sweep within the ambit of the Act any disparaging comment made in the context of a commercial transaction. The plain meaning of § 43(a)(2) does not permit this interpretation.").

Additionally, the annotation simply does not support Ferring's allegation that Braintree's superiority and efficacy claims are baseless. Although Ferring complains that the annotation is incorrect because Phase 3 clinical trials for Prepopik establish that its efficacy is greater than 74%, *nowhere* does Ferring allege – let alone prove – that, even if higher than 74%, Prepopik's efficacy is as high as or higher than Suprep's. Regardless of the correct figure, there is simply no evidence that Suprep's 98% efficacy rate is superior to Prepopik's. Ferring has failed to adduce a *shred* of evidence to the contrary.

Ferring has also offered no basis to show that the annotation is even reasonably attributable to Braintree. Indeed, Ferring's proffered evidence that the annotation was made by a Braintree sales representative is nothing more than inadmissible hearsay – specifically, a statement by a Ferring sales representative that she was told by an unidentified doctor than an unidentified Braintree sales representative wrote the statement. (*See* Wilmer Decl. ¶ 13.) As described above, (*see* supra at I.B), such hearsay – and, especially, hearsay upon hearsay – is insufficient to defeat a motion for summary judgment. *See, e.g.*, *Bennett*, 507 F.3d 23 at 28-29; *Davila*, 498 F.3d at 17; *Garside*, 895 F.2d at 50.

C. Ferring Cannot Defeat Summary Judgment on the Basis of Mere Allegations.

Finally, Ferring once again resorts to rote recitation of its complaint's *allegations* that Braintree falsely and misleadingly represented that Suprep is safer than Prepopik. But, as described above, (*see* supra at I.B), in so doing, Ferring ignores black-letter law that "[t]he party opposing a property supported motion for summary judgment . . . may not rest upon mere allegation or denials of his pleading," and fails to set forth *any* specific facts showing that there is a genuine issue for trial. *Nna*, 630 F. Supp. at 124. Indeed, Ferring's opposition offers no discussion

of any evidence in support of its allegations. Ferring's burden was to adduce evidence – not mere allegations – to support its claims. It failed to do so.

Accordingly, this Court should grant Braintree's summary judgment motion on the basis of Ferring's failure and inability to adduce any admissible evidence that Braintree's superiority and efficacy claims were actually false, misleading, or "baseless."

III. FERRING'S STATE TRADEMARK DILUTION CLAIM AGAINST A COMPETITOR IS LEGALLY FLAWED.

Ferring's complaint clearly sets forth a theory of state trademark dilution premised on the allegations that Braintree has made false statements to the effect that Prepopik is unsafe and insufficiently effective, thus disparaging Prepopik. Having apparently learned from Braintree's opening brief that a plaintiff cannot base a Massachusetts trademark claim on a competitor's disparaging commentary, as the statute applies only to dilution claims, Ferring tries to reinvent its state-law claim. Now, Ferring says that the claim is premised on a theory of dilution through association of Ferring's Prepopik mark with Ferring's own Pico-Salax mark. In other words, the alleged dilution claim is apparently not that Braintree attempts to sell its own product under the Prepopik mark or a confusingly similar mark, but that Braintree is tarnishing one of Ferring's marks – Prepopik – by calling it another of Ferring's marks – Pico-Salax.

Nothing in the Massachusetts statute or caselaw interpreting it allows for this novel theory that a competitor-defendant can be liable for causing confusion not between the competitor-defendant's own product and the plaintiff's mark, but between two of the plaintiff's marks by pointing out that the products to which the marks refer are the same. While Ferring may have good reason to fear that if consumers understand that its Prepopik brand refers to the same product as its Pico-Salax brand they may be less inclined to buy Prepopik, pointing out that the two are the same is not an actionable dilution of the Prepopik mark under Massachusetts law.

Nor does Ferring's cited case law in any way suggest that Massachusetts law (or any other dilution law for that matter) covers such a theory. Far from supporting its theory, for example, the First Circuit's holding in *Universal Communications Systems, Inc. v. Lycos, Inc.*, 478 F.3d 413 (1st Cir. 2007), is directly contrary to Ferring's new theory. First, the First Circuit addressed Florida's, not Massachusetts's, anti-dilution act. But more importantly, the court did not uphold a dilution claim, but rather held that the plaintiff's allegations did *not* state a valid dilution claim because the alleged harm did not result in an "improper association between the mark and *products or services by others*." *Id.* at 423 (emphasis added). The same is true here, as there is no allegation that Braintree is causing any dilution by associating the mark at issue, Prepopik, with the products of another. In *Santander Consumer USA Inc. v. Walsh*, 762 F. Supp. 2d 217 (D. Mass. 2010), another opinion on which Ferring relies, the Court addressed a claim that defendant used a name for *its* financial-services products that was confusingly similar to the trademarked name for plaintiff's financial-services products – i.e. a classic dilution claim based on confusingly similar names for *competing* products. Ferring's only other cited opinion is of a similar type, involving a competitor-defendant's use of the plaintiff's mark on the competitor-defendant's products. *S & H Indus., Inc. v. Selander*, 932 F. Supp. 2d 754, 764 (N.D. Tex. 2013) (applying Texas law and holding that "[t]arnishing addresses instances in which *a defendant uses a trade name* similar to that of the plaintiff *on products* that are markedly inferior or of a different quality and nature than those of the plaintiff." (emphasis added; internal quotation marks omitted)).

Finally, even if the Massachusetts anti-dilution statute supported the theory that Ferring now puts forward, the theory would suffer from the exact same evidentiary problems discussed above that preclude Ferring's Lanham Act claims. Given Ferring's admissions about the

equivalency of Prepopik and Pico-Salax, and the lack of admissible evidence regarding other alleged comments, any dilution claim based on Braintree's equating Ferring's own marks with one another fails for lack of record support, even were it legally tenable. In reality, Ferring confused its own products by equating them and cannot separate the "dilution" it may have caused when doing so from any other confusion based on others repeating Ferring's own purported misstatements.

CONCLUSION

For the foregoing reasons and the reasons provided in Braintree's opening brief, Braintree respectfully requests that the Court grant summary judgment dismissing all counts brought by Ferring with prejudice.

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Respectfully submitted,
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CERTIFICATE OF SERVICE

I hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing ("NEF") on June 9, 2014.

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